Attachment 9

- 510(k) - Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	***LungCare CT***
	Software Package with extended functionality
Common Name	3D CT Reconstruction Software
Classification Name:	Accessory to Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:
Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 Erlangen, Germany

4. Contact Person:

Mr. Rüdiger Körner
Regulatory Submissions
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-9355
Fax: +49 9191 18-9988

5. **Date of Preparation of Summary**: September 19th 2003

K033374

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Substantial Equivalence:

The **LungCare CT** software package with extended functionality, adressed in this premarket notification, is substantially equivalent to the following commercially available software package

Manufacturer	Product	510(k)	Clearance date
1. Siemens	LungCare CT Software	K022013	July 16, 2002

In summary, Siemens is of the opinion that LungCARE CT software package with extended functionality does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

8. Device Description and Intended Use:

This premarket notification covers Siemens LungCARE CT software package with extended functionality. It is based on Siemens syngo software platform.

This premarket notification covers Siemens LungCARE CT - Software package with extended functionality. LungCARE CT is a self-contained image analysis software package for evaluating CT volume data sets. Combining enhanced commercially available digital image processing tools (MIP, MPR SSD, VRT), evaluation tools (volumetric estimation using consistent standardised measurement protocol, comparator tool for lesion matching by synchronisation of two datasets, classification of lesions using configurable descriptors) and reporting tools (targeted presets, saved lesion location) with optimised workflow palette. The LungCare CT Software Package with extended functionality contains modifications which support the user with a special workflow based on automated segmentation for the visual identification of possible lesions (Nodule enhanced Viewing).

This software package is designed to support the physician in confirming the presence or absence of physician identified lung lesions (e.g. lesions) in addition to evaluation, documentation and follow-up of any such lesions using standard or low-dose spiral CT scanning. This visualisation tool allows for volumetric analysis of pulmonary lesion or lesion size over time, helping the Physician to assess the

changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.

The enhanced part of the LungCARE CT software package provides an extended evaluation of segmentation by displaying all connected voxels above a certain HU (Hounsfield-Unit) threshold. The system will now indicate the voxels of equivalent signal level and calculate the contours of the suspicious lesion/lesion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

Siemens AG Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K033374
Trade/Device Name: LungCare CT Software Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: OEB
Dated: October 16, 2003
Received: October 22, 2003

Dear Mr. Preiss:

This letter corrects our substantially equivalent letter of November 6, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indication for use

510(k) Number (if known): K033374

Device Name: ***LungCare CT*** - Software Package with extended functionality

LungCARE CT is a self-contained image analysis software package for evaluating CT volume data sets. Combining enhanced commercially available digital image processing tools with an optimized workflow and reporting tools, the software is designed to support the physician in confirming the presence or absence of physician identified lung lesions (eg. nodules) in addition to evaluation, documentation and follow-up of any such lesions using standard or low-dose spiral CT scanning. The LungCare CT Software Package with extended functionality contains modifications which support the user with a special workflow based on automated segmentation for the visual identification of possible lesions (Nodule enhanced Viewing).

This visualization tool allows for volumetric analysis of pulmonary nodule or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously having determined their size, dimensions, shape and position.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

(Per 21 CFR §801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033374